The opinion in support of the decision being entered today was <u>not</u> written for publication and is not binding precedent of the Board.

Paper No. 46

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte W. ROY KNOWLES

Appeal No. 2004-2301 Application No. 09/619,142 MAILED

MAR 3 0 2005

U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

ON BRIEF

Before GARRIS, WARREN, and DELMENDO, <u>Administrative Patent</u> Judges.

DELMENDO, Administrative Patent Judge.

DECISION ON REHEARING

This is in response to the appellant's request for rehearing pursuant to 37 CFR § 41.52(a)(1) (2004)(effective Sep. 13, 2004), filed on Feb. 25, 2005 (paper 45), of our Jan. 7, 2005 decision (paper 44). In our original decision, we affirmed the examiner's rejections under:

I. 35 U.S.C. § 112, ¶1, of appealed claims 1 through 5, 7 through 16, and 18 through 22 as failing to comply with the written description requirement;

- II. 35 U.S.C. § 102(b) of appealed claims 1 through 4 and 12 through 15 as anticipated by U.S. Patent 5,183,817 issued to Bazzano on Feb. 2, 1993;
- III. 35 U.S.C. § 102(b) of appealed claims 1, 3, 12, and 14 as anticipated by U.S. Patent 5,015,470 issued to Gibson on May 14, 1991;
- IV. 35 U.S.C. § 102(b) of appealed claims 1, 2, 12, and 13 as anticipated by U.S. Patent 4,440,777 issued to Zupan on Apr. 3, 1984;
- V. 35 U.S.C. § 103(a) of appealed claims 2, 4, 5, 7 through 10, 13, 15, 16, and 18 through 21 as unpatentable over Gibson in view of Bazzano or U.S. Patent 5,373,012 issued to Schostarez on Dec. 13, 1994; and
- VI. 35 U.S.C. § 103(a) of appealed claims 11 and 22 as unpatentable over Bazzano in view of U.S. Patent 5,192,534 issued to Grollier et al. on Mar. 9, 1993. (Original decision at 4-23.)

The appellant's only argument in the request for rehearing (page 1) is stated in its entirety as follows:

The point believed misapprehended in the original decision is that the claim term "penetration enhancer" expressly exempts polyethylene glycol and ethanol.

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Withdraw [sic] of all grounds of rejection is accordingly believed required as a matter of law.

This argument is unpersuasive. For proper perspective, we start with a brief review of our basis for affirming the examiner's prior art rejections. In our original decision, we pointed out that:

- 1. Bazzano teaches a topical lotion formulation containing, <u>inter alia</u>, 0.5 to 5.0% by weight of minoxidil, q.s. to 100% by weight of ethanol, and 5.0 to 50.0% by weight of propylene glycol (decision at 12);
- 2. Gibson teaches cosmetic and pharmaceutical composition containing, <u>inter</u> <u>alia</u>, 2% by weight of minoxidil, 70% ethanol, and 10% propylene glycol (decision at 15-16);
- 3. Zupan teaches a progesterone, which is undisputedly a 5α -reductase inhibitor, in combination with eucalyptol (or other penetration enhancers) for treating alopecia (decision at 18-19); and
- 4. (a) U.S. Patent 5,482,965 issued to Rajadhyaksha on Jan. 9, 1996, (b) Zupan, and (c) CAPLUS Abstract AN 1998:223670 of Stephen A. Mikulak, Thomas C. Vangsness, and Marcel E. Nimni, "Transdermal delivery

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and accumulation of indomethacin in subcutaneous tissues in rats," 50(2) J. PHARMACY & PHARMACOLOGY 153-58 (Apr. 22, 1998) (hereinafter "Mikulak") teach that ethanol, propylene glycol, and a 50:50 (volume/volume) mixture of propylene glycol and ethanol, respectively, are known to possess penetration enhancing properties (decision at 12-13).

On the basis of these factual findings, we held that the burden of proof was properly shifted to the appellant to show that the ethanol and propylene glycol disclosed in Bazzano and Gibson would not inherently or necessarily aid the minoxidil in penetrating the skin surface to a depth of approximately the depth of hair bulbs, as recited in appealed claim 1. (Decision at 12-13 and 15-16.) In addition, we were not persuaded by the appellant's argument against Zupan that the reference "teaches drug delivery completely through the skin" as opposed to "a depth of approximately the depth of hair bulbs." (Decision at 18.) Specifically, we determined that complete penetration of the drug would necessarily result in penetration to "a depth of approximately the depth of hair bulbs."

The appellant fails to point to anything (and we find nothing) in either the language of the appealed claims or the

description in the specification to warrant a conclusion that the term "non-retinoid penetration enhancer" excludes ethanol, which is disclosed in Bazzano and Gibson.

Because we find no merit in the appellant's argument, we decline to modify our original decision in any respect. The appellant's request for rehearing is granted to the extent of reconsidering our original decision on the record but is denied with respect to making any substantive changes thereto.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR \S 1.136(a).

DENIED

Bradley R. Garris
Administrative Patent Judge

Charles F. Warren

Administrative Patent Judge

BOARD OF PATENT

APPEALS AND

INTERFERENCES

Romulo H. Delmendo

Administrative Patent Judge

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